Reconsideration of the restriction requirement is requested, particularly in view of the instant claims. The "method" of the instant invention cannot be performed with out using the "blood sample" (termed "preparation" in claims 1-18) of the instant invention. Therefore, restriction under 35 USC 121 does not apply.

Reconsideration is requested for the rejections made of record under 35 USC 112, second paragraph, in view of the changes to the claims reflected in the instant amendment and the following remarks..

Applicants submit that determination of a blood reaction (blood response) is performed by well known biological, physical, chemical and/or physicochemical methods (see specification, page 5). Biological test procedures are well-known procedures of the type explained on page 1 of the specification. "Immuno-related data" and "immuno-functional data" are terms used, interchangeably, for data concerning immunoactivators, immunostimulators, immunotoxicity, immunomodulators, immunotherapeutics, and immunosupressors. This is the field of immunopharmacology.

The blood "response" (or reaction) comprises the immunorelated data determined by the well known methods, explained above, upon contacting blood with the test material. In accordance with the presently claimed method, thawed cryopreserved whole blood, e.g., in presence of diluents, anticoagulants, buffers and

so on, has to be used. The material tested is exemplified on pages 1-2 of the specification, i.e., "materials and objects comprising medications, blood substituents, blood replacements, and/or devices." The cryopreserved whole blood after thawing is the reagent to determine immunorelated actions, if any, in contact with the test material.

Reconsideration is requested for the rejections made of record under 35 USC 102.

None of the references cited in the statements of rejection teaches or suggests cryopreserved whole blood; even less does any of the references teach or suggest the claimed method starting from cryopreserved whole blood.

Sobota et al. experiment with cryopreserved lymphocytes (see Abstract).

Busch et al. perform HIV tests with cryopreserved mononuclear blood cells (Abstract; "Methods," pages 1-3).

Durrant et al. deals with tumor killing in patients using cryopreserved lymphocytes (Abstract; "Materials and Methods," "Clinical Protocol," page 4837).

Martin et al. uses a specifically prepared cryopreserved Pro Granulocyte-Makrophage cell line (SPGM-1 cell line) (column 1, lines 13-61; column 5, lines 40-41; Examples 1 and 2).

Venkataraman uses cryopreserved mononuclear cells (Abstract and page 165).

What applicants discovered is, that in cases where whole blood is required as a biological system for blood response, the test of any material must be started quite often without delay; and in any case, started within a few hours. That leaves no time for thorough checking of the reactivity of the whole blood used; and, therefore, it is impossible to reliably rule out incorrect results caused by using whole blood from a donor with abnormal reactions, such as might be caused by genetic variations, disease, or life style, with dangerous consequences. In testing individual lots of pharmaceuticals, for example, the danger of improper transportation or storage often requires that, even under emergency conditions, the pharmaceutical to be administered must be tested before use. But, for the reasons noted, above, when fresh blood is used, it may not be possible to exclude whole blood with abnormal reactions or to a compare it with previous test results with sufficient reliability.

One of the objects of the present invention is, accordingly, assuring a smooth and reproducible procedure, ruling out the possibility of error due to abnormal reactions; and, moreover, pointing out a way that allows test results to be compared with earlier test results using the same test material, with the same whole blood, under controlled conditions. The presently claimed invention provides that repeated tests at various sites be standardized and made possible at various times.

The use of the cryopreserved whole blood according to the presently claimed invention makes it possible to have available, at any time, whole blood which has been previously tested and so is free of abnormal reactions. At a minimum, it can be standardized and then used as a standard reagent. As a large number of completely identical cryopreserved units can be prepared from one lot of blood, the requirement for reproducibility of tests at different times and places can be satisfied. Furthermore, characterization of one such lot with data relevant to the testing opens up a route for comparison with results from use of different lots of whole blood that have also been adequately characterized. Whole blood samples diluted with, for example, cell culture media, buffers, or clinical sodium chloride solution can be used.

Due to cryopreservation it is possible to use identical units of whole blood, repeatedly, at different times and places. Abnormal blood reactions can be recognized in appropriate preliminary tests, and the corresponding whole blood can be removed. Standard values for the particular lot of blood can be determined in advance under standardized conditions. It makes it possible to do testing even if it is not immediately possible to draw whole blood.

Favorable action commensurate with the foregoing is requested.

Respectfully submitted,

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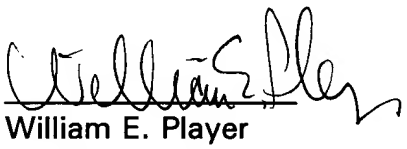

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